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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,643	05/23/2005	Catherine Castan	022290.0120PTUS	1869

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PATTON BOGGS LLP
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EXAMINER	
HELM, CARALYNNE E	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
03/25/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,643	CASTAN ET AL.	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 7-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/2/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Communication*.

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
10510643	5/23/2005	CASTAN ET AL.	022290.0120PTUS

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EXAMINER	
CARALYNNE HELM	
ART UNIT	**PAPER**
1615	20090319

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

37 CFR 1.105 REQUIREMENT FOR INFORMATION:

Applicant (or the assignee of this application if the assignee has undertaken the prosecution of the application) is required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

There are numerous other co-pending applications and issued patents, which disclose and claim very similar and/or identical subject matter. In accordance with 37 CFR 1.105 and MPEP 704.11(a) subsection G, applicant (or the assignee) is respectfully requested to disclose all co-pending applications and related patents (please see the non-exhaustive list below of applications and issued patents that the USPTO believes may be related) and identify the specific claims of those applications and/or patents which may present double patenting issues with the instant application claims. This requirement is reasonably necessary to examination because, based on an initial review of the applications, there is a significant degree of overlap in claimed subject matter, thus requiring an analysis of commonality of claimed subject matter to determine patentability under 35 USC 101 double patenting and/or obviousness type double patenting. For example, claims 1-2, 8-9, 11, 14-16, and 26 of application 11/449675 differ from claims 1-3, 9-10, and 24-26 of application 10/510643 in only the obvious variation of proportions of coating components and saturation of the liquid vehicle with drug as taught by Carvais (US Patent No. 4,902,513). Because the applicant (or the assignee) is presumably far more cognizant of the contents of the claims in these applications than any Office staff, and has access to the source documents by which such comparison could be done better than within the Office, it is reasonable to require the applicant to provide the information needed to determine the commonality among the claims.

Should applicant (or the assignee) believe that Double Patenting exists, then applicant (or the assignee) is invited to file Terminal Disclaimers and/or amend the currently pending claims in the interest of expediting the prosecution of the current application. Applicant (or the assignee) should note that a terminal disclaimer is effective to overcome an obviousness type double patenting rejection, but will not overcome a "same type" double patenting rejection under 35 U.S.C. § 101.

Non-exhaustive list of possible related co-pending applications and patents:
10/580037, 10/826690, 10/996780, 10/997836, 11/358047, 11/439247, 11/449675, 11/648605, 11/651577,11/723553, 11/791466, 11/802610, 11/883935, 11/884534, 11/884549, 11/920741.

/Caralynne Helm/
Examiner, Art Unit 1615

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically the claim now recites stearic acid or oleic acid as surfactant or lubricant choices. There was no previous discussion of either of these compounds being present in the claimed composition, therefore this new recitation is new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 2 recites “stearate” then recites “preferably calcium, magnesium, aluminum, or zinc stearate". This embedded limitation within a limitation renders the claim indefinite.

Claim 2 also recites “an alkaline metal earth metal salt of a fatty acid”. It is unclear whether this is supposed to be an alkaline metal salt of a fatty acid or an alkaline earth metal salt of a fatty acid.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 4-5, 7-10, 15, 17-19, and 24-26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-17 and 19-31 of copending Application No. 10/522,252 in view of Carvais. Both the instant application and application 10/522,252 teach an oral suspension of a drug (both teach many of the same classes and particular drugs, including naproxen, ganciclovir, and morophine) containing microcapsules coated at 1% to 50% (by mass) with a film comprising a film forming polymer insoluble in gastrointestinal tract fluid, a nitrogen containing polymer, a plasticizer, and a surfactant/lubricant. Both also teach that the microcapsules are less then 1000 μm in size. Application 10/522,252 does not teach that the liquid phase of the suspension is saturated with the drug. Carvais teaches a suspension of drug that contains microcapsules of the drug, present at about 5%, and whose liquid phase is saturated with the drug. One of ordinary skill in the art at the time the invention was made would have found it obvious to use the teachings of Carvais to

modify the invention of application 10/522,252 to practice the instant invention to have a product capable of instant as well as prolonged drug delivery.

Claims 1-3, 5, 7-10, 17, 19, and 24-26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9, 11-24, 26, 31, 41-50, 58-76, 89-91, 99-101, and 113 of copending Application No. 11/707,034 in view of Carvais. Both the instant application and application 11/707,034 teach an oral suspension of a drug containing microcapsules coated with a film comprising a film forming polymer insoluble in gastrointestinal tract fluid, a nitrogen containing polymer, a plasticizer, and a surfactant and/or a lubricant. Both also teach that the microcapsules are less then 1000 μm as well as the inclusion of anti-viral drugs. Application 11/707,034 does not teach that the liquid phase of the suspension is saturated with the same drug contained in the microcapsules. Carvais teaches an oral suspension of drug that contains microcapsules of the drug and whose liquid phase is saturated with the drug. One of ordinary skill in the art at the time the invention was made would have found it obvious to use the teachings of Carvais to modify the invention of application 10/707,034 to practice the instant invention in order to have a product capable of instant as well as prolonged drug delivery.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of Graham v. John Deere Co. have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 7-12, 17-19, and 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carvais (previously cited) in view of Autant et al. (US Patent No. 6,022,562).

Carvais teaches a sustained release liquid oral suspension that comprises a suspension with microcapsules of a drug suspended in a saturated solution of the drug, where dissolution of the microcapsules maintains the saturation level of drug in solution (see column 1 lines 26-38; instant claims 1, 5, 7-8, and 19). Dissolution of the microcapsules over time as drug is removed from the liquid brings the concentration in the liquid back to the level of saturation (instant claims 5 and 23). This liquid phase is taught to be either non-aqueous or aqueous (see column 1 lines 18-19 and 21-23). Carvais also teaches that the invention is suitable for drugs that run the spectrum from water insoluble to water soluble (see column 1 lines 16-25). In one embodiment, Carvais teaches that 158.33 mg of drug is suspended in 5 ml of water vehicle which translates to about 3% microcapsules and 97% vehicle (see example I). Carvais teaches that this amount of drug in suspended form can be adjusted upward (see example I; instant claims 21-22). A subsequent example does just this where approximately 5% microcapsules is in about 95% vehicle (see example III; instant claims 4 and 21-22). Beyond the drug to be included, Carvais does not teach a particular microcapsule composition.

Autant et al. teach a set of coated particles (microcapsules) that contain any number of active principle components (drugs) (see abstract). In particular, the coating is taught to be composed of the following components:

1. “at least one film-forming polymer (PI) which is insoluble in the liquids of the digestive tract, present in a quantity of 50 to 90%, preferably 50 to 80% by weight of dry matter of the whole coating composition, and consisting of at least one

non-hydrosoluble cellulose derivate, ethylcellulose and/or cellulose acetate being preferred;

2. at least one nitrogen-containing polymer (P2), present in a quantity of 2 to 25, preferably 5 to 15% by weight of dry matter of the whole coating composition, and consisting of at least one polyacrylamide and/or one poly-N-vinylaride and/or one poly-N-vinyl-lactam, the polyacrylamide and/or the polyvinylpyrrolidone being preferred;

3. at least one plasticizer present in a quantity of 2 to 20%, preferably 4 to 15% by weight of dry matter of the whole coating composition, and consisting of at least one of the following compounds: glycerol esters, phthalates, citrates, sebacates, cetylalcohol esters, castor oil and cutin, castor oil being particularly preferred;

4. at least one surface-active and/or lubricating agent, present in a quantity of 2 to 20%, preferably 4 to 15% by weight of dry matter of the whole coating composition, and chosen from anionic surfactants, preferably the alkali metal or alkaline-earth metal salts of fatty acids, stearic acid and/or oleic acid being preferred, and/or from nonionic surfactants, preferably polyoxyethylenated esters of sorbitan and/or polyoxyethylenated esters of sorbitan and/or polyoxyethylenated derivatives of castor oil, and/or from lubricants such as stearates, preferably calcium, magnesium, aluminum or zinc stearate, or such as stearylfumarate, preferably sodium stearylfumarate, and/or glyceryl behenate, said agent comprising only one or a mixture of the above products" (see column 6 line 55-column 7 line 32; instant claims 1 and 2).

A particular coating embodiment combines ethyl cellulose, poly(vinyl pyrrolidone), castor oil and magnesium stearate (see column 16 lines 38-48; instant claim 2). The particles are taught to have a size of "between 50 and 1000 microns, preferably of between 100 and 750 microns and, more preferably, of between 100 and 500 microns" (see column 7 lines 33-35; instant claims 9 and 24-25). Autant et al. go on to teach that

the coating constitutes 5 to 40% by weight of the particles and is applied in a single layer (see column 11 lines 59-61 and column 12 lines 12-13; instant claims 3, 10, and 26). A listing of active principle compounds that are envisioned within the particles are taught by Autant and all of these compounds are also claimed by applicant (see column 10 lines 55-65; instant claims 17-18).

The only detail provided by Carvais about the microparticles in the taught suspension is the presence of drug, thus these particles must be coated, uncoated, or a collection of both coated and uncoated particles. Since sustained release of drug is a main goal of the Carvais invention, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Autant et al. with Carvais and prepare a suspension with drug saturating the aqueous vehicle and including coated drug particles. This combination would result in two embodiments, the first where only the coated particles of Autant et al. are used as the microcapsules in Carvais and the second where the coated particles of Autant et al. are included with uncoated particles. Autant et al. teaches that their coated particles provide sustained release and protection for the contained active principle from the gastrointestinal environment such that the active principle is delivered to the small intestine, the preferred location for systemic absorption (see column 3 line 60-column 4 line 5). Such a coated particle would therefore be desirable in the suspension of Carvais who also teaches sustained release for the drug in its suspension. In addition, since the combined references teach embodiments with the same drug and coating, as well as the same proportions of drug, coating components and coated particles as that taught

by the applicant, absent any evidence to the contrary, the function claimed by the applicant would also be present in the invention of the Carvais in view of Autant et al. (see instant specification example 2). Thus, the limitations of claims 11-12 and 27 are also taught by Carvais in view of Autant et al. Therefore, claims 1-5, 7-12, 17-19, and 21-27 are obvious over Carvais in view of Autant et al.

Claims 1-2, and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carvais in view of Autant et al. as applied to claims 1-5, 7-12, 17-19, and 21-27 above, and further in view of Turck et al. (US Patent No. 6,184,220).

Carvais in view of Autant et al. makes obvious an aqueous suspension saturated with drug and containing either coated drug particles or both coated and uncoated drug particles, where the coating contains the claimed constituents. This modified reference does not explicitly teach particular components other than water in the liquid vehicle (see instant claims 1-2).

Turck et al. teach a liquid drug suspension where many of the drugs are also claimed in the instant claims (see abstract and column 5 lines 16-20). Turck et al. teach a liquid medium for this suspension whose pH is between 2 and 4 that comprises buffering agents (solubility modifier), sweetener, glycerol (rheology modifier), and water soluble cellulose polymer (rheology modifier) (see column 8 lines 26-36 and 42-46; instant claims 13-16). It would therefore have been obvious to one of ordinary skill in the art at the time the invention was made to induce an acidic pH and include a solubility modifier, rheology modifier or sweetener in the aqueous vehicle of Carvais in view of

Autant et al. since these were known components and properties used in oral liquid dispersion media. Therefore claims 1-2 and 13-16 are obvious over Carvais in view of Autant et al. and Turck et al.

Claims 1 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carvais in view of Autant et al. as applied to claims 1-5, 7-12, 17-19, and 21-27 above, and further in view of Ulrich et al. (previously cited).

Carvais in view of Autant et al. makes obvious an aqueous suspension saturated with drug and containing either coated drug particles or both coated and uncoated drug particles, where the coating contains the claimed constituents. This modified reference does not explicitly teach a kit configuration for the suspension components (see instant claims 1-2).

Ulrich et al. teach a suspension of coated drug particles (see abstract). Ulrich teach that a dry powder form of the coated drug can be provided for later reconstitution with a liquid vehicle (kit) (see paragraph 34 line 7-9; instant claim 20). Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to configure the suspension components of Carvais in view of Autant et al. as a dry preparation of coated and uncoated particles and a separate liquid vehicle. The proportions of the uncoated and coated particles would have been obvious to one of ordinary skill in the art so as to produce a saturated liquid vehicle with suspended coated particles. Thus, claims 1 and 20 are obvious over Carvais in view of Autant et al. and Ulrich et al.

Response to Arguments

Applicant's arguments filed December 19, 2008 have been fully considered but they are not persuasive.

Rejections under 35 USC 103 (a):

Due to the amendment to the claims new grounds of rejection are cited in the office action, however arguments regarding Carvais, utilized in the new rejections, are addressed below.

Applicant argues that Carvais teaches that the saturated aqueous solution controls the sustained release of drug to the blood stream. Actually in the phrase quoted by applicant, Carvais teaches "…a suspension comprising microcapsules of said drug suspended in a saturated solution of said drug, the saturated level of said drug being maintained over a prolonged period of time for sustained release to the bloodstream and at a substantially constant level by means of the dissolution of the microcapsules into solution to replace the drug that leaves said solution, thereby maintaining the saturated level of drug in solution." (see column 1 lines 30-38). Therefore the microcapsules of Carvais do in fact control the sustained release of drug into the bloodstream. Applicant also argues that the instant claims would not have been obvious over the combined references because one of ordinary skill in the art would not have combined the elements as claimed and recognized the difficulty in preparing a drug suspension. Applicant also characterizes the arguments presented in the Office action incorrectly, appearing to have confused the instant case with the copending

application 10/510621 which claims amoxicillin only while the instant claims explicitly exclude amoxicillin. According to MPEP 2144 IV, the reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. Applicant's arguments regarding the remaining references are moot in view of the new grounds of rejection.

Provisional Nonstatutory-type obviousness rejections:

Regarding the rejection of claims 1-2, 4-10, 15, and 17-19 over claims 16-17 and 19-31 of copending Application No. 10/522252 in view of Carvais, applicant argues that the instant claims would not have been obvious over the combined references because one of ordinary skill in the art would not have combined the elements as claimed and recognized the results were predictable. Applicant also characterizes the arguments presented in the Office action incorrectly, appearing to have confused the instant case with the copending application 10/510621 which claims amoxicillin only while the instant claims explicitly exclude amoxicillin. According to MPEP 2144 IV, the reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. In addition, applicant also argues that the microcapsules of copending application 10/522252 are not taught in a suspension when claim 30 explicitly recites an

aqueous suspension as a final product form for the claimed microcapsules. Applicant further argues that the teachings of the microcapsules of copending application 10/522252 run counter to the instant invention because they are described to release their drug contents within 12 to 24 hours. However when combined with the invention of Carvais, the release of drug from the microcapsules of copending application 10/522252 would occur when the drug is below its saturation level in the liquid medium; thereby functioning the same as the microcapsules of the instant invention. Applicant also argues that Carvais teaches that the saturated aqueous solution controls the sustained release of drug to the blood stream. Actually in the phrase quoted by applicant, Carvais teaches "…a suspension comprising microcapsules of said drug suspended in a saturated solution of said drug, the saturated level of said drug being maintained over a prolonged period of time for sustained release to the bloodstream and at a substantially constant level by means of the dissolution of the microcapsules into solution to replace the drug that leaves said solution, thereby maintaining the saturated level of drug in solution." (see column 1 lines 30-38). Therefore the microcapsules of Carvais do in fact control the sustained release of drug into the bloodstream.

Regarding the rejection of claims 1-3, 5-10, 17, and 19 over claims 1-9, 11-24, 26, 31, 41-50, 58-76, 89-91, 99-101, and 113 of copending Application No. 11/707034 in view of Carvais, applicant argues that the copending application does not teach microcapsules and that their taught release of drug in 8 to 16 hours runs counter to the instant invention. Instant claim 1 provides no size restrictions on the "microcapsules".

Although applicant may have intended a particular range for these particles, the “micro” prefix does not in and of itself require a particular size. In fact, any length measurement can be expressed in micrometers thereby allowing any sized capsule to be reasonably classified as a "microcapsule". When combined with the invention of Carvais, the release of drug from the microcapsules of copending application 10/707034would occur when the drug is below its saturation level in the liquid medium; thereby functioning the same as the microcapsules of the instant invention. Applicant further argues that Carvais teaches that the saturated aqueous solution controls the sustained release of drug to the blood stream. Actually in the phrase quoted by applicant, Carvais teaches “…a suspension comprising microcapsules of said drug suspended in a saturated solution of said drug, the saturated level of said drug being maintained over a prolonged period of time for sustained release to the bloodstream and at a substantially constant level by means of the dissolution of the microcapsules into solution to replace the drug that leaves said solution, thereby maintaining the saturated level of drug in solution.” (see column 1 lines 30-38). Therefore the microcapsules of Carvais do in fact control the sustained release of drug into the bloodstream. In addition, applicant argues that the instant claims would not have been obvious over the combined references because one of ordinary skill in the art would not have combined the elements as claimed and recognized the results were predictable. According to MPEP 2144 IV, the reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by

applicant. Furthermore, in a suspension where a drug is present in an encapsulated form and saturates the liquid medium one would expect that there would not be a major issue of drug being release during storage. Without subjecting the suspension to extreme conditions (e.g. that which would yield supersaturation, an unstable saturation state), the liquid medium would already contain the most dissolved drug it could carry, and thus there would be no concentration gradient to drive or prompt the release of the encapsulated drug. Even if there were a non-extreme shift in temperature during storage that increase the solubility limit of the drug in the liquid vehicle, the amount of encapsulated drug dissolution would likely be minimal.

Any rejections not reiterated from the previous Office action are hereby withdrawn.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
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